United States Senate Committee on Finance

UPDATE — COPY-PASTED HERE IS THE NEW VERSION OF THE LETTER TO PhRMA FROM SENS. GRASSLEY, BAUCUS, HATCH AND ROCKEFELLER. THIS NEW VERSION WAS SENT TO PhRMA TO REPLACE THE FIRST ONE SENT TODAY, WHICH WAS INCLUDED IN THE NEWS RELEASE EMAILED TO YOU. FOR YOUR REFERENCE, THAT NEWS RELEASE FOLLOWS THE LETTER.

April 21, 2006

The Honorable Wilbert J. Tauzin, Jr.
President and CEO
PhRMA
950 F Street, NW
Washington, DC 20004

Dear Mr. Tauzin:

We are writing to express our concern about the recent announcements made by some pharmaceutical manufacturers that they plan to curtail their patient assistance programs (PAPs) because of the perceived lack of clear federal guidance on operating a PAP now that Medicare's prescription drug benefit has become available. Millions of Americans, including Medicare beneficiaries, receive invaluable assistance in getting their prescription drugs through patient assistance programs offered by several PhRMA member companies. Many of these medications are extremely costly and without assistance from a PAP, some Medicare beneficiaries may not otherwise be able to afford them, even if they are enrolled in the new Medicare prescription drug benefit.

Last November, the Department of Health and Human Services Office of the Inspector General (OIG) issued guidance regarding potential approaches for operating a PAP in the new Medicare prescription drug benefit environment. We understand that, for some pharmaceutical manufacturers, the OIG's November guidance did not provide enough clarity regarding the legality of PAPs in relation to the new Medicare prescription drug benefit. However, we believe the PAP model approved by the OIG earlier this week provides substantial clarification regarding the ways pharmaceutical manufacturers can structure their PAPs around the Medicare prescription drug benefit. Moreover, the OIG issued a statement in the November guidance indicating the OIG would exercise discretion in taking enforcement actions against pharmaceutical manufacturers operating PAPs this year -- the initial year of the Part D benefit. These facts make a company's decision to end its PAP as of May 15 seem rather arbitrary.

We are happy that some companies have already announced that they will continue their

PAPs. Merck and Schering-Plough have announced they will continue their patient assistance programs, which indicates that legal and feasible avenues for operating a PAP alongside the Medicare prescription drug benefit do exist. While Schering-Plough is the only company that has received an OIG advisory opinion to date, we are aware that other pharmaceutical companies have made such requests. The Schering-Plough model provides a workable roadmap for how a PAP can be operated going forward. It is, however, a floor and not a ceiling of possible options. A company that wants to pursue an alternative structure for its PAP could request an individual Advisory Opinion from the OIG.

We applaud Merck and Schering-Plough for their commitment to their patient assistance recipients, who rely on their products to maintain their health. We wholeheartedly agree with PhRMA's statement that the OIG opinion on Schering-Plough's PAP, "can provide useful guidance to other companies." In your capacity as President and CEO of PhRMA, we implore you to call on other member companies to expeditiously develop approaches – as Merck and Schering-Plough did – to continue their PAPs. It is simply unacceptable for any pharmaceutical company to use the launch of the new Medicare prescription drug benefit as an excuse to limit their PAPs as of May 15, particularly since there is now clear legal guidance from the OIG on ways to operate these programs.

If there are outstanding legal concerns about the ability of pharmaceutical companies to continue to operate PAPs, then we would like to know about them. Otherwise, we strongly encourage your member companies to find legal avenues for continuing these vital patient assistance programs, and we would appreciate your informing us about the actions PhRMA is taking to educate it members about such avenues.

Sincerely,

Charles E. Grassley
Chairman

Max Baucus
Ranking Minority Member

Orrin G. Hatch
Chairman
Health Care Subcommittee

John D. Rockefeller IV
Ranking Minority Member
Health Care Subcommittee

For Immediate Request
Friday, April 21, 2006

Senators keep focus on keeping drug assistance for Medicare beneficiaries

WASHINGTON — Leading senators are urging pharmaceutical drug makers to continue offering prescription drugs to Medicare beneficiaries through programs designed to help individuals with high prescription drug costs.

Sens. Chuck Grassley, Max Baucus, Orrin Hatch, and John D. (Jay) Rockefeller IV also have pressed for the Inspector General for the Department of Health and Human Services to issue clear guidance addressing the legal concerns of pharmaceutical manufacturers about offering drug assistance programs after May 15, when the first sign-up period ends for Medicare's new prescription drug benefit.

We've got a situation where it looks like the May 15 date has become an excuse for dropping the assistance that many Medicare beneficiaries rely on, and that's not right," Grassley said. The Inspector General issued more guidance earlier this week, and some companies have announced that they'll continue their programs, so legal avenues do exist."

"Pharmacy assistance programs provide invaluable assistance to people working hard to get by," said Baucus. "The Medicare prescription drug benefit does not prevent drug companies from continuing to provide this help to those in need, and the Inspector General has made that clear. I hope that drug companies resolve their concerns and continue to provide this much needed help."

"Drug companies now have the green light to complement the new Medicare program with their assistance programs, and I encourage them to continue giving generously to help our seniors," Hatch said.

"Now that the Inspector General has provided some concrete guidance, it's time for pharmaceutical companies to fulfill their obligation," said Rockefeller. "Simply put, these companies should not halt this vital assistance to Americans who cannot afford the prohibitively expensive prescription drugs they need in order to survive. The lives of many Americans depend on these companies being good citizens."

The text of the Senators' letter to PhRMA, the association representing the nation's leading pharmaceutical research and biotechnology companies, follows here, along with statements made earlier this week about an advisory from the Inspector General, and the text of a letter sent on Monday from Grassley, Baucus, Hatch and Rockefeller to the Inspector General.

April 21, 2006

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President and CEO
PhRMA
950 F Street, NW
Washington, DC 20004

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We are happy that some companies have already announced that they will continue their PAPs. Merck, Schering-Plough, and AstraZeneca have all announced they will continue their patient assistance programs, which indicates that legal and feasible avenues for operating a PAP alongside the Medicare prescription drug benefit do exist. While Schering-Plough is the only company that has received an OIG advisory opinion to date, we are aware that other pharmaceutical companies have made such requests. The Schering-Plough model provides a workable roadmap for how a PAP can be operated going forward. It is, however, a floor and not a ceiling of possible options. A company that wants to pursue an alternative structure for its PAP could request an individual Advisory Opinion from the OIG.

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If there are outstanding legal concerns about the ability of pharmaceutical companies to

continue to operate PAPs, then we would like to know about them. Otherwise, we strongly encourage your member companies to find legal avenues for continuing these vital patient assistance programs, and we would appreciate your informing us about the actions PhRMA is taking to educate it members about such avenues.

Sincerely,

Charles E. Grassley
Chairman

Max Baucus
Ranking Minority Member

Orrin G. Hatch
Chairman
Health Care Subcommittee

John D. Rockefeller IV
Ranking Minority Member
Health Care Subcommittee

M E M O R A N D U M

TO: Reporters and Editors
RE: IG Advisory Opinion
On Pharmaceutical Manufacturer Patient Assistance Programs
DA: April 18, 2006

Yesterday, Sens. Chuck Grassley, Max Baucus, Orrin Hatch, and John D. (Jay Rockefeller) asked the Inspector General for the Department of Health and Human Services for guidance to address the legal concerns of drug makers who participate in patient assistance programs. The Inspector General issued an opinion today. Comments from individual senators follow here.

"It's good to finally have this advisory opinion from the Inspector General. The company who made the request now knows that its program to help Medicare beneficiaries meets federal rules and requirements. I urge the Inspector General to provide similar assurance to other companies quickly as the May 15 deadline is fast approaching. Those companies also need to provide any additional information requested by the Inspector General in a timely way." -- Senator Chuck Grassley

"I'm glad the HHS Inspector General was able to advise one drug manufacturer on how to continue its patient assistance program properly in conjunction with the Medicare drug benefit. I trust that other companies seeking advice and assistance will get timely help from the IG, so they

can keep their programs going. It's good that the pharmaceutical manufacturer involved has found a way to continue providing this much-needed assistance, and I hope that others in the industry can do the same so that financially needy Medicare beneficiaries can get the drugs they need." -- Senator Max Baucus

"The Inspector General's office made a good start today by clarifying for one company the legal parameters for operating a PAP. But more needs to be done. In the coming days, the Inspector General must give clear guidance to other drug manufacturers and to the free clinics also awaiting a decision. Hundreds of thousands of Medicare recipients are scared that they will not be able to afford the prescription drugs they need. We must make sure that these programs are still there to help our seniors." -- Senator John D. (Jay) Rockefeller IV

For Immediate Release
Monday, April 17, 2006

Senators seek continued assistance from drug companies for Medicare beneficiaries

WASHINGTON - Top health care policy makers in the U.S. Senate have asked for prompt and definitive guidance from the government to help ensure that Medicare beneficiaries with extraordinary needs can continue to access additional assistance from pharmaceutical drug makers even after signing up for the new Medicare prescription drug benefit.

At issue is the continued availability of pharmaceutical manufacturer patient assistance programs, known as PAPs. Sens. Chuck Grassley, Max Baucus, Orrin Hatch and John D. (Jay) Rockefeller IV have urged the Inspector General for the Department of Health and Human Services to make a clear statement as soon as possible addressing the legal concerns of drug manufacturers so that the additional drug assistance that helps so many individuals through these PAPs is not discontinued after May 15, the deadline for Medicare beneficiaries to sign up for the new Medicare drug benefit.

"Clear-cut guidance is needed to help maintain the drug assistance that many older Americans rely on, and we've been working to get that guidance for several months," Grassley said. "These Medicare beneficiaries have extraordinary health care needs."

"Many seniors simply wouldn't get the drugs they need without patient assistance programs, so it's important that the government quickly provide appropriate advice on how these programs can mesh with the new Medicare drug benefit," said Baucus. "I believe it's possible to discourage Medicare fraud without discouraging drug manufacturers from providing these vital programs, and I know the Inspector General will seek to strike a balance that works."

"We have been pushing for a resolution on this issue since November," said Rockefeller. "We are less than a month away from having some drug companies terminate these vital

programs, and yet our seniors still have no assurance that they will be able to get the prescription drugs they need from these programs. Nothing short of an immediate and complete clarification of these rules is acceptable."

The text of the Senators' letter to the Inspector General follows here.

April 17, 2006

Mr. Daniel R. Levinson, Inspector General
Department of Health and Human ServicesRoom 5541 Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Inspector General Levinson,

We are writing to express our support for the continued availability of pharmaceutical manufacturer patient assistance programs (PAPs). As you know, manufacturer PAPs provide free or subsidized medications to thousands of individuals, including Medicare beneficiaries, who might not otherwise be able to afford their prescription drugs. Many seniors and individuals with disabilities who participate in manufacturer PAPs have chronic conditions. These beneficiaries must take very expensive prescription drugs - which often do not have generic drug equivalents - to manage those conditions and to maintain their quality of life. Without assistance from a PAP, some Medicare beneficiaries may not otherwise be able to afford their prescription drugs, even if they are enrolled in the new Medicare prescription drug benefit.

We appreciate that your office issued the Special Advisory Bulletin on Patient Assistance Programs last November. The goal of this Bulletin was to clarify the applicability of the federal anti-kickback statute to all PAPs, including those offered by pharmaceutical manufacturers. Unfortunately, it is our understanding that the Bulletin may have had the opposite effect. As a result, several pharmaceutical manufacturers have indicated that they will discontinue their prescription assistance to Medicare beneficiaries as of May 15.

Your office has achieved significant accomplishments in reducing waste, fraud and abuse in the Medicare Part A and Part B programs. We applaud the OIG's efforts in assisting, developing and implementing a comprehensive strategy to identify and prevent fraud, waste and abuse under Medicare Part D. Working with the Centers for Medicare and Medicaid Services (CMS), the Federal Bureau of Investigation (FBI) and prosecuting attorneys at the Department of Justice (DOJ), the OIG has recognized the importance of protecting Medicare beneficiaries and taxpayers' dollars. That said, we are troubled that the OIG's Guidance may limit-albeit unintentionally-beneficiary access to necessary medications. We are particularly concerned about the ongoing availability of manufacturer PAPs for three groups of Medicare beneficiaries: 1) low-income beneficiaries of limited means who do not qualify for the low-income subsidy; 2) low-income beneficiaries between 135 percent and 150 percent of poverty who qualify for the low-income subsidy, but pay 15 percent coinsurance for their prescriptions; and 3) higher-income beneficiaries with catastrophic prescription drug needs who currently derive a significant benefit

from participation in pharmaceutical manufacturer PAPs.

It is our understanding that some companies have requested advisory opinions from the OIG regarding the legality of the specific design of their PAPs. We understand that this process is iterative and that the OIG often must ask the requester for additional information. We hope, though, that the OIG will continue to work as expeditiously as possible in responding to these requests, which may help mitigate this situation. Again, we urge you to work to further clarify the legal guidance on the manufacturer PAPs as expeditiously as possible. We believe a resolution can be achieved that allows pharmaceutical manufacturers to continue providing much needed assistance to certain groups of Medicare beneficiaries in a manner that does not violate the integrity of the Medicare program.

We thank you for your prompt attention to and consideration of this request. Because of the seriousness of this matter, we are instructing our staff to contact your office Monday to discuss this issue further.

Sincerely,

Charles E. Grassley
Chairman

Max Baucus
Ranking Minority Member

Orrin G. Hatch
Chairman
Health Care Subcommittee

John D. Rockefeller IV
Ranking Minority Member
Health Care Subcommittee

cc: Michael Leavitt, Secretary, Health & Human Services